

FOR IMMEDIATE RELEASE
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CIRM Contact: Nicole Pagano
(415) 396-9100

**Opening Statement by Sherry Lansing, Co-Chair
of the Scientific and Medical Accountability Standards Working Group,
on the Draft Regulations for Research Funded
by the California Institute for Regenerative Medicine**

LOS ANGELES, CA – "I THINK WE CAN GET STARTED. FIRST OF ALL, I'D LIKE TO WELCOME ALL OF YOU AND TELL YOU THAT OVER THE NEXT TWO DAYS, WE WILL BE COMING TO A CLOSURE, AS MOST OF YOU KNOW, ON A REGULATORY PACKAGE THAT WILL THEN BE SUBMITTED TO THE ICOC. AND I HAVE TO SAY I BELIEVE THIS IS REALLY A MILESTONE, AND IT'S REALLY A EMARKABLE ACHIEVEMENT.

AND I CAN'T HELP BUT REFLECT BACK ON WHEN WE ALL STARTED TOGETHER AS A GROUP AND ALSO THE MEMBERS OF THE PUBLIC THAT HAVE CONSISTENTLY BEEN HERE AND OBVIOUSLY THE LEGISLATURE. ALL OF US HAVE WORKED TOGETHER. WE WORKED TOGETHER TO FORM, WHICH I THINK YOU WILL SEE, AND OBVIOUSLY THIS IS THE WORK OF THE NEXT TWO DAYS, THE STRONGEST REGULATORY PACKAGE IN THE COUNTRY, IN THE HISTORY OF THE COUNTRY.

WE DID JUST WHAT WE SAID WE WERE GOING TO DO. WE TOOK THE NAS GUIDELINES AND WE DID NOT RUBBER-STAMP THEM. WE DID NOT JUST SAY, WELL, THIS IS GOOD ENOUGH, BUT WE WENT ABOVE AND BEYOND THAT AND WE IMPROVED THEM. ON A PERSONAL LEVEL, I WANT TO SAY THAT IT HAS BEEN A TRUE PRIVILEGE AND HONOR FOR ME TO WORK WITH ALL OF YOU. AND I MEAN THE STANDARDS GROUP AND I ALSO MEAN THE PUBLIC AND THE LEGISLATURE. AND NONE OF THIS WOULD HAVE HAPPENED WITHOUT ALL THREE OF US WORKING TOGETHER.

I FIRST WANT TO THANK THE MEMBERS OF THE STANDARDS GROUP BECAUSE I AM VERY, VERY GRATEFUL TO ALL OF THE WORK THAT YOU DID. AND I WANT TO REMIND EVERYBODY WHAT A DISTINGUISHED GROUP WE HAVE ON THE STANDARDS GROUP, ON OUR COMMITTEE, THE HIGHEST LEVEL OF EXCELLENCE. AND JUST TO REMIND EVERYBODY, WE HAVE TWO MEMBERS OF THE UNITED STATES NATIONAL BIOETHICS ADVISORY COMMITTEE. WE HAVE TWO MEMBERS OF THE BLUE RIBBON COMMITTEE THAT DEVELOPED THE NAS GUIDELINES FOR EMBRYONIC STEM CELL RESEARCH. WE HAVE MEMBERS OF THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCE, MEMBERS OF THE AMERICAN ACADEMY OF ARTS AND SCIENCES, HOWARD HUGHES MEDICAL INSTITUTE FELLOWS, AND OBVIOUSLY ICOC BOARD MEMBERS WHO ARE RECOGNIZED FOR THEIR PATIENT ADVOCACY AND THEIR POLICY BUILDING.

IT'S AN EXTRAORDINARY GROUP, AND THE ACCOMPLISHMENTS THAT THESE PEOPLE HAVE SPEAK FOR THEMSELVES, BUT I ACTUALLY FOUND OUT THAT THE COMMITTEE MEMBERS ALONE HAVE PRODUCED OVER 1,000 PEER-REVIEWED MANUSCRIPTS IN THE AREAS OF THEIR RESEARCH. I THINK THAT'S JUST AN ASTOUNDING STATISTIC. SO I WANT TO THANK ALL OF YOU FOR YOUR COMMITMENT, FOR YOUR TIME, FOR YOUR ENERGY, AND FOR YOUR PASSION.

THIS MEETING TODAY AND TOMORROW WILL CULMINATE SEVEN MONTHS OF WORK. AND IT'S SEVEN MONTHS OF WORK BY EVERY SINGLE MEMBER. THERE WASN'T A PERSON WHO DIDN'T PARTICIPATE FULLY IN IT. JUST TO REMIND YOU, WE HAD FIVE PUBLIC MEETINGS. AND EQUALLY AS IMPRESSIVE TO ME IS THE COUNTLESS HOURS,

WHICH I CAN'T EVEN BEGIN TO ENUMERATE HOW MANY THERE WERE BETWEEN THE MEETINGS, WHERE WE WENT THROUGH THE VARIOUS DRAFTS AND OVER THE DRAFT AND OVER THE DRAFT, AND THAT'S IN ADDITION TO ALL OF YOUR PROFESSIONAL RESPONSIBILITIES. MOST OF YOU TRAVELED FROM OUT-OF-STATE, AND THAT ADDS TO THE TIME THAT YOU ALSO SPENT.

AND I ALSO WANT TO THANK PARTICULARLY THE ICOC MEMBERS WHO, IN ADDITION TO THIS, MANY OF US PARTICIPATED IN MOST OF THE 57 PUBLIC MEETINGS THAT THE ICOC HAD -- I SEE JEFF'S FACE -- FOR THE PAST 14 MONTHS. THIS DEDICATION AND THIS TIME WAS EXTRAORDINARY. AND WITHOUT THIS, WE WOULD NOT HAVE BEEN ABLE TO IMPROVE THE NAS GUIDELINES.

AGAIN, I REALLY WANT TO SAY WE ADOPTED GUIDELINES ON AN INTERIM BASIS AND WE MADE THEM BETTER. WE WENT BEYOND WHAT THE NAS GAVE US. BUT I ALSO WANT TO REMIND ALL OF US THAT OUR WORK IS CONTINUAL, AND WE ARE A CONTINUAL WORK IN PROGRESS. AND TODAY, IN MY OPINION, NOT TODAY, I SHOULD SAY TOMORROW HOPEFULLY WILL MARK THE END OF THE BEGINNING, THE END OF THE FIRST PHASE OF WHAT WE'RE DOING, BUT OUR GROUP IS NOT DISBANDING. OUR GROUP IS CONTINUING TO WORK. AS THE SCIENCE TEACHES US NEW THINGS, AS THINGS EVOLVE, WE WILL CONTINUE TO MAKE IMPROVEMENTS ON OUR POLICY.

I ALSO WANT TO THANK THE CALIFORNIA LEGISLATURE BECAUSE THEY REALLY DID HELP US IN FORMING OUR POLICY AND OUR DELIBERATIONS. AGAIN, YOU WILL SEE WE ARE IN COMPLETE AGREEMENT ABOUT INFORMED CONSENT, AND OBVIOUSLY WE REJECT HUMAN REPRODUCTIVE CLONING. THE LEGISLATURE HAS BEEN A TREMENDOUS HELP TO US AND WE ARE ALL VERY, VERY GRATEFUL FOR THEIR INPUT.

AND FINALLY I WANT TO THANK THE PUBLIC. A LOT OF YOU ARE HERE TODAY, SOME OF YOU WE CORRESPONDED WITH THROUGH E-MAIL. YOUR CONSISTENT MONITORING, YOUR CONSISTENT INPUT, YOUR CONSISTENT ADVOCACY HAS LED US, I BELIEVE, TO THESE POLICIES. WE HAD THREE PUBLIC SESSIONS IN ADDITION TO THE FIVE PUBLIC MEETINGS. AND THESE PUBLIC SESSIONS, AND A LOT OF YOU HERE TODAY WERE PART OF THOSE, WERE LIVELY. THERE WAS A GREAT DEAL OF DIALOGUE BETWEEN THE MEMBERS OF THE GROUP AND THE PUBLIC. THE INPUT WAS INVALUABLE, IT WAS TRANSPARENT, AND IT WAS INCLUSIVE. AS I SAID, WE ALSO HAD FIVE PUBLIC MEETINGS, AND THEN WE DID ALL OF THIS IN ADVANCE OF THE COMMENTS THAT WE RECEIVED FROM THE FORMAL PUBLIC COMMENT PERIOD. THOSE COMMENTS WE ALL RECEIVED, AND WE ALL, EVERY SINGLE MEMBER OF THE GROUP, PAID ATTENTION TO, AND AGAIN, I HAVE TO SAY THOSE INPUTS, AND I SPEAK ON BEHALF OF ALL OF US, WERE INVALUABLE TO US IN MAKING THE POLICY. SO FOR ME, WORKING WITH THE PUBLIC HAS BEEN A TREMENDOUS HELP, AND I THINK I SPEAK FOR ALL US IN SAYING THAT, AS WELL WORKING WITH THE LEGISLATURE AND OBVIOUSLY WORKING WITH ALL OF YOU AND CONTINUING TO WORK WITH ALL OF YOU, IT'S BEEN A TRUE PRIVILEGE IN MY LIFE.

I ALSO THINK I WOULD BE REMISS IF I DIDN'T SPEAK ON BEHALF ALL OF US HERE TODAY TO SAY HOW SAD AND SHOCKED AND DISMAYED WE WERE AT WENT ON WITH DR. HWANG IN KOREA AND THE FRAUD THAT WAS PERPETRATED THERE. THIS DECEPTION NOT ONLY AFFECTED DR. HWANG, BUT IT ALSO AFFECTED MANY OTHER PEOPLE WHO WERE HIS COLLABORATORS, PEOPLE WHO DEPENDED ON HIM. AND ONE OF THOSE PEOPLE WHO WAS AFFECTED WAS DR. JOSE CIBELLI, WHO WAS ONE OF THE MANY CO-AUTHORS IN HIS FIRST SCIENCE PAPER IN THE YEAR 2004. BUT AS SOON AS DR. CIBELLI DISCOVERED THAT SCIENTIFIC FRAUD WAS AN ISSUE, HE PERSONALLY ASKED FOR AN INDEPENDENT INVESTIGATION AT MICHIGAN STATE UNIVERSITY. HE ASKED FOR THIS. AND HE ASKED FOR THIS TO DETERMINE WHETHER

OR NOT HE HAD BEEN GUILTY OF ANY WRONGDOING. AND AT THE SAME TIME DR. CIBELLI CONTACTED US AT THE CIRM, AND HE INDICATED HIS DESIRE TO VOLUNTARILY WITHDRAW FROM THE STANDARDS WORKING GROUP. AND HE DID THIS BECAUSE HE DIDN'T WANT THIS ACTION IN ANY WAY TO REFLECT ON OUR GROUP. WE HAVE OBVIOUSLY ACCEPTED HIS WITHDRAWAL, AND WE -- AND NONE OF US SHOULD DRAW JUDGMENT ON THIS UNTIL WE KNOW THE FACTS AND UNTIL THE INVESTIGATION IS COMPLETED. IT'S HIS WITHDRAWAL UNTIL THE INVESTIGATION IS COMPLETED.

BUT THAT RAISES THE QUESTION IS HOW DO WE PROTECT OURSELVES AGAINST THE SAME THING HAPPENING HERE? AND I HAVE TO SAY, ONCE AGAIN, THAT WE CAN ONLY CONTROL OUR WORLD, BUT BY SETTING THESE STANDARDS, WE'RE LEADING THE WORLD, AND WE HOPE THAT EVERYBODY ELSE WILL ADOPT THESE STANDARDS, WHICH WILL GO A LONG WAY IN STOPPING SUCH A SITUATION FROM HAPPENING AGAIN. SO LET US REMIND OURSELVES OF WHAT WE HAVE DONE TO PREVENT SOMETHING LIKE THIS FROM HAPPENING.

FIRST OF ALL, AS I SAID, WE STARTED WITH THE STRONG ETHICAL GUIDELINES OF THE NAS, BUT WE IMPROVED THEM. WE WENT BEYOND THEM. WE MADE THEM MORE STRINGENT, AND WE DIDN'T JUST ACCEPT THEM AND RUBBER-STAMP THEM.

ADDITIONALLY, WE HAVE MORE LEVELS OF OVERSIGHT. WE HAVE OUR DISTINGUISHED GROUP OF OUT-OF-STATE RESEARCHERS WHO PRESENT AND OVERSEE SCIENTIFIC PEER REVIEW; AND BECAUSE THEY'RE OUT-OF-STATE, THERE IS NO CONFLICT OF INTEREST AND THEY CAN REMAIN COMPLETELY OBJECTIVE. THEN AFTER THEY'VE DONE THEIR PEER REVIEW, WHICH IS THE FIRST LEVEL OF OVERSIGHT, IT GOES TO THE ICOC 29-MEMBER BOARD. AND THAT BOARD REVIEWS IT. AND YOU WILL SEE THAT THAT BOARD, EVEN IN OUR INITIAL GRANTING PROCESS, DOES NOT JUST RUBBER-STAMP IT. IT CAN AGREE, IT CAN DISAGREE, IT CAN QUESTION. SO THAT'S A SECOND LEVEL OF OVERSIGHT.

AND THEN FINALLY, THE CIRM STAFF IS BOUND BY OTHER GROUPS. WE DON'T EXIST IN A VACUUM, SO WE HAVE THE CHECKS AND BALANCES OF THE SCIENTIFIC PEER REVIEW, OF THE GRANTS ADMINISTRATION, OF INTELLECTUAL PROPERTY, AND OUR OWN STANDARD GROUP. SO WE ARE NOT EXISTING IN A VACUUM. THAT'S THE THIRD LEVEL OF OVERSIGHT.

AND SO BECAUSE OF THIS, I THINK WE'RE DOING EVERYTHING THAT IS HUMANLY POSSIBLE TO PREVENT SOMETHING LIKE THIS FROM HAPPENING. BUT AGAIN, I WANT TO SAY WE'RE A WORK IN PROGRESS. SO WE CONTINUE, AS OTHER THINGS HAPPEN, TO SEE IF WE NEED TO DO SOMETHING ELSE IN ADDITION. FINALLY, I JUST WANT TO SAY AGAIN AN ENORMOUS THANK YOU TO ALL OF YOU HERE TODAY IN THE PUBLIC, IN THE LEGISLATURE, AND ON THE STANDARDS WORKING GROUP.

THE AMOUNT OF TIME, COMMITMENT, AND PASSION THAT YOU HAVE GIVEN US IS EXTRAORDINARY; BUT, AGAIN, THIS IS JUST THE END OF THE BEGINNING. OUR WORK CONTINUES. IT'S A NEW FIELD, AND WE'RE CONSTANTLY GOING TO BE ADAPTING AND CHANGING, BUT THIS FIRST STEP IS A MONUMENTAL ONE.

SO WITH THAT SAID, I'D LIKE TO HAVE A ROLL CALL."